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Abstract

Progressive resistance plus balance training (PRBT) has been demonstrated as effective in reducing later life physical disability, falls risk and poor health, even among those with complex health care needs. However, few studies have examined the influence of PRBT on health service utilisation, cognitive wellbeing and training modality acceptance or undertaken a cost benefit analysis. This project will investigate the broad scope benefits of PRBT participation among community-dwelling older Australians receiving Government supported aged care packages for their complex health care needs. Using a modified stepped-wedge design, 248 community-dwelling adults 65 years and older with some level of government support aged care have been randomised into the study. Those randomised to exercise undertake six months of twice weekly machine-based, moderate to high intensity, supervised PRBT, followed by a six month unsupervised, unsupported follow-up. Controls spend six months undertaking usual activities, before entering the PRBT and follow-up phases. Data are collected at baseline and after each of the six month phases. Measures include level of and change in health and care needs, body composition, muscle capacity, falls, sleep, quality of life, nutritional and mental health status. In addition, acceptance and engagement is determined through telephone and focus group interviews complementing a multi-model health cost benefit evaluation. It is hypothesised this study will demonstrate the feasibility and efficacy of PRBT in improving primary and secondary health outcomes for older adults with aged care needs, and will support the value of this modality of exercise as an integral evidence-based service model of care.

Keywords: aged care; disability; exercise; health care costs; older adults; resistance training.

Abbreviations:

AEP	Accredited exercise physiologist
BIA	bioelectrical impedance analysis
CHSP	Commonwealth Home Support packages
CON	control group
EX	exercise group
GDS	Geriatric Depression Scale
GAI	Geriatric Anxiety Inventory
GP	General practitioner
HCP	Home Care Packages
MMSE	Mini-Mental State Examination
MNA	Mini-Nutritional Assessment instrument
PRBT	progressive resistance plus balance training
RAC	residential aged care
RM	Research manager
SPPB	Short Physical Performance Battery
SVHA	St Vincent's Health Australia

1. Introduction

1.1. Background

Like many developed and developing nations, Australia's ageing population will bring with it many challenges and place major stresses on the healthcare system due to increases in disability and prevalence of complex health conditions (Goss, 2008). When coupled with increasing intensive care service needs and the growth of the population 85 years and over, projected health care expenditure will soar and by 2050 the demand for home assist and residential aged care (RAC) placement will more than treble (Productivity Commission, 2011). Presently in Australia, greater than one million older adults receive government supported home care services each year (Productivity Commission, 2011). In addition to government supported care, some 2.7 million Australians provide family care giver services to prevent their spouse or loved one's transition in to RAC. Even with family care givers offering home support, increases in disability and care needs can have an associated 700% increase in expenditure when older adults transition from a lower level of support to a higher aged care package (Lewin, Alfonso, & Alan, 2013). As the median cost of a three-year Home and Community Care (HACC) support package for an individual reported to be $11,365 (Lewin et al., 2013), any large-scale uptake of these HACC services places a large burden on the Australian health care expenditure.

While associated with increasing age, the decline in health and increased disability experienced by older adults may be closely related to the degree of sedentary behaviour and the development of the geriatric condition sarcopenia (Keogh, Senior, Beller, & Henwood, 2015; Senior, Henwood, Beller, Mitchell, & Keogh, 2015). With these changes in muscle composition, capacity and mobility comes an increased risk of disability, cognitive impairment, institutionalisation, and/or early mortality (Abellan van Kan et al., 2013; Fielding et al., 2011; Sánchez-Rodríguez et al., 2014). The question then becomes: How do healthcare professionals delay these age-related health and functional declines and attenuate transition of community-dwelling older adults into Government supported aged care packages and/or RAC? We propose the answer to this question is through age-friendly, community-based, cost–effective exercise programs that have a strong focus on progressive resistance plus balance training (PRBT).

Evidence is strong that older adults with a history of extended sedentary behaviour can reduce their disability needs and falls risk, and improve their general health and quality of life as a result of increasing their physical activity levels (Brett, Traynor, & Stapley, 2016; Denison, Cooper, Sayer, & Robinson, 2015). As an in-home model of care, physical activity orientated restorative and re-ablement services are associated with improved physical function and falls-reduction among older adults with complex health care needs (Burton, Lewin, Clemson, & Boldy, 2013; Clemson et al., 2012). However, while the research evidence surrounding this model is positive, programs are often

short-term, not well based in evidence and may not be cost-effective as they require the time-intensive input of multiple health professionals working with one client on multiple occasions. Moreover, questions still remain about the feasibility of translating restorative care research into practice by care providers in contrast to provision by a research centre, especially if such care programs involving one-on-one interactions between therapists and clients can be delivered in a more cost-effective manner (Ryburn, Wells, & Foreman, 2009).

Progressive resistance training is a powerful mode of exercise that produces a plethora of significant muscle physiology and health benefits for old and very old, community-dwelling and institutionalised adults (Henwood, Riek, & Taaffe, 2008; Valenzuela, 2012). It is the only exercise mode shown to reduce many of the adverse effects associated with normal ageing, including the reduction in physical disability and chronic diseases such as diabetes, osteoporosis and osteoarthritis, all of which are known to predispose the older person towards home and/or aged care service need (Crocker et al., 2013). When coupled with targeted balance exercise, progressive resistance training is suggested a significant countermeasure to latter life's disability and falls risk (Sherrington, Tiedemann, Fairhall, Close, & Lord, 2011; Sherrington et al., 2008). Progressive resistance plus balance training (PRBT) can be undertaken safely by older adults, independent of age, level of illness and disability, with community and RAC studies of high-intensity participation reporting increased muscle strength, mobility, bone mineral density, sleep and physical performance, and reduced disability, falls risk and depression (Chin, van Uffelen, Riphagen, & van Mechelen, 2008; Portero & Couillandre, 2011; Valenzuela, 2012). So powerful is participation in this form of training that gains in functional health are reported to remain for up to six months after the training stimulus is removed (Henwood & Taaffe, 2008).

When compared to currently available aged care services such as HACC, physical activity orientated restorative and re-ablement services have been demonstrated to be cost-effective, with three-year savings of ~$9000 per individual (Lewin et al., 2013). However, these restorative and re-ablement services are typically only provided for between 8-12 weeks and generally involve the interaction of multiple healthcare professionals with each client in one-on-one sessions (Lewin et al., 2013). This raises a question of whether community-based PRBT exercise programs may be a more cost-effective approach to reduced disability-related healthcare costs in older adults with reduced muscle function and limited mobility. As sarcopenia can increase hospitalization costs by 34% for older patients (Sousa et al., 2016) and as PRBT can significantly reduce disability and falls in older adults with mobility limitations (Gillespie et al., 2012; Liu & Latham, 2011), the focus of this intervention was on determining the cost effectiveness of a community, group-based PRBT program in such a population. We propose that such an intervention will not only protect the wellbeing of the client and prolong their capacity for greater levels of self-care, but have significant implications for the health care expenditure. Specifically, reducing the need for accessing care packages and the

current rapid transition from level 1 - 4 will reduce Australia aged care spending significantly. When coupled with the expected reduced residential and hospital service utilisation, and pharmaceutical needs, major savings to the projected age- and disability-related increase in healthcare expenditure could be obtained within the next two decades (AIHW, 2014).

1.2 Hypothesis

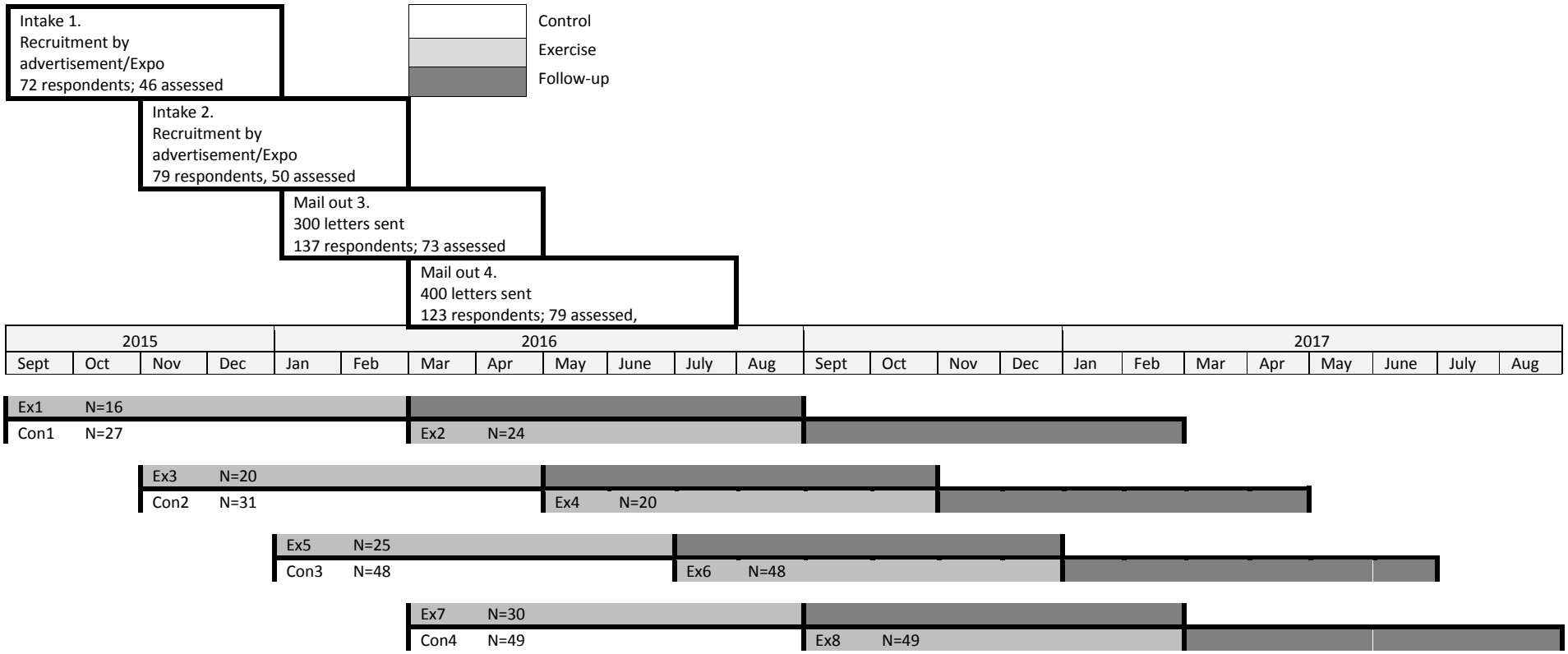
We hypothesise that the performance of six months of moderate to high-intensity PRBT by older Australians accessing Government supported aged care packages will prove cost-effective for reducing their trajectory of health decline as well as improving and prolonging their functional wellbeing, with benefits retained for up to 24 weeks after the training period.

2. Methods

2.1 Trial design and protocol

Funding for the described investigation was secured at the beginning of 2015, with the first of four delivery phases beginning in September of 2015. To this end, the projected timeline of this investigation is from September 2015 until August 2017 when those randomised into the control group in phase 4 will finish their 24-week follow-up period. An overview of the intakes (phases), inclusive of responders to recruitment drives, the number consented to baseline assessment, the randomisation breakdown and groups project commitment, are given in Figure 1. With the remainder of this trial protocol, all phases of the study that have been completed are set in the past tense, and those yet to be completed set in the future tense.

Figure 1. Study recruitment and randomisation with focus on mail out seeking expressions of interest, uptake, randomisation and study entry.



2.1.1 Study type and setting

The project employed a modified stepped-wedge randomised control design to ensure all 248 participants experienced the opportunity to benefit from PRBT. To ensure feasibility of the sample recruitment, assessment and program delivery, the project was completed in multiple phases (N = 4). Phases saw individuals undergo a baseline assessment prior to being randomised to either the exercise (EX) or wait list control (CON) groups; and then be assessed every 24-weeks until all groups had completed a 24 weeks' post-intervention follow-up period. Randomisation was conducted by assigning each client a sequential client ID number upon arrival for assessment and then matching that number to a computer randomised sequence held by the Research Manager (RM) created by one of the research team not involved in the baseline assessment. Randomisation occurred following baseline assessment and was by block randomisation using an onsite sealed envelope selection method. No stratification was utilised in this randomisation approach.

All CON group participants become the EX group following the 24-week intervention period. To ensure training sessions did not become over crowded, randomisation was at a 1:2 EX:CON ratio. Based on the current randomisation schedule, 248 individuals will serve as exercise participants with training and the follow-up data, and 155 participants will serve as controls to the study. Project assessments are conducted and PRBT delivered at two Burnie Brae Senior Citizen Centre sites (Chermside or Bracken Ridge) on the north side of Brisbane, Queensland, Australia (Burnie Brae Inc, www.burniebrae.org.au). Participants attended the location closest to their home. These Burnie Brae facilities are Community Centres specifically targeted to older adults offering a variety of social and physical activities to their members; also having in place procedures for addressing adverse incidents and are risk-assessed to ensure client safety. The exercise areas in the Burnie Brae centres are dedicated spaces for this project, with each site undergoing further risk assessment to ensure it was accessible and hazard free for the target group.

2.1.2 Eligibility criteria

a. **Inclusion.** Participants eligibility for this study were as follows:

1. Possess a current Australian Home Care Package (level 1 to 4) or Commonwealth Home Support Package (equivalent to HACC package)
2. Aged ≥ 65 years
3. Community-dwelling
4. Mobile with or without an aid
5. Able to follow instructions
6. Able to commit to the 24-week training period
7. No history of resistance training in the past 6 months

b. **Exclusion.** Participants were excluded if they meet any of the following criteria:

1. Require assistance from ≥ one person in transfer to standing
2. Possess a Re-ablement or Restorative Commonwealth Home Support package
3. Have an advanced falls risk
4. Have a terminal/palliative status with ≤ 12 months to live
5. Have medications or disease with exercise contraindications
6. Have no consent (GP or substitute-decision maker)
7. Are projected to move into a residential aged care facility
8. Are difficult to work with as a consequence of behavioural issues

2.1.3 Recruitment, transport, consent, ethical considerations and trial registration

Recruitment was through both the Burnie Brae and St Vincent's Health Australia (SVHA) membership. Specifically, for Burnie Brae, individuals were approached by newsletter, website advertising and personalised letters penned and signed by the organisation's CEO, with a request to contact the RM with an expression of interest. SVHA is a large Australian non-profit aged care provider that provide services to older adults living in community and in residential aged care. For SVHA, individuals were approached directly by their organisational personal carer, who informed them about the project and opportunity, and requested an expression of interest to participate. Following the expression of interest, the RM contacted the individual by telephone to determine eligibility. The questions asked by the RM in the telephone discussion allowed the RM to provide conditional entry into the program and to give a broader overview of the project, set an assessment date for entry into the project and organise transport for those who would require it. Following the telephone conversation with the RM, potential participants were screened at one of the Burnie Brae centres by an AEP. The AEP focused on criteria such as advanced falls risk, with this defined as an inability to self-mobilise in a safe and steady manner. This assessment was made by an observation of the potential participants' gait and general mobility and a series of related questions if required. To facilitate adherence and overcome a barrier to participation, all participants are offered free minibus return transport for all assessment and training sessions using the Burnie Brae transport service. This is organised and scheduled by the RM, and the schedule determined through discussion with the participant.

Prior to the baseline assessment and entering the study, participants supplied informed consent. General practitioner (GP) consent was also obtained prior to participation. This involved gaining verbal consent from the participant to contact their GP during the initial telephone interview, and then the RM directly mailing the GP with details of the study, the name of the participant and a request for the GP to respond to the RM if they felt any concerns about the participant entering the

exercise program. Ethics approval was obtained from the University of Queensland Human Research Ethic Committee (Approval number #2015000879) and Gatekeepers approval through the SVHA Human Research Ethic Committee (Approval reference HREC 15/21). Following the finalisation of the study design and ethics approval, the study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615001153505).

2.1.4 Intervention

Exercise consisted of twice weekly machine-based resistance and free standing balance training for 24 weeks under the close supervision of Accredited Exercise Physiologists (AEP) experienced in exercise delivery to older adults with complex health care needs. Exercise session are proceeded by a low intensity five-minute warm-up using ergonomic walking, sit to stands, arm or leg cycling, or machine rowing, and followed by a five-minute warm-down that includes targeted stretching. Within each session participants performed several resistance exercises using air-pressure driven machines proven effective in older disabled adults (HUR Australia Pty Ltd, Birkdale, QLD, Australia) and balance exercises targeting static and dynamic balance, and agility (Henwood et al., 2008; Sherrington et al., 2008). Resistance exercises are:

- Upper-body – Chest press and Back row;
- Lower-body – Leg press; Leg curl/extension and Abduction/adduction; and
- Core – Abdominal/back extension.

All exercises are performed for 3 sets of 8-12 repetitions.

Balance exercises are:

- Static standing on one leg (left and right) - 2 sets of aiming for 20 seconds on each leg;
- Tight rope walking - 2 sets of 10 steps forward and 10 steps back, and
- Box stepping - 5 times clockwise and 5 times anticlockwise.
- Calf raises - 2 sets of 10

For individuals experiencing pain or discomfort when performing a particular exercise, the exercise in question was modified where possible. If a modification did not alleviate the pain or discomfort the exercise was removed completely and not replaced by an alternative. All exercises and the machine on which PRBT occurred have been demonstrated to be safe and effective in this and older more disabled populations previously (Henwood et al., 2008; Hewitt, Refshauge, Goodall, Henwood, & Clemson, 2014).

To ensure technique development and reduce training related delayed on-set of muscle soreness, participants undertake a four-week conditioning phase prior to training at a higher-intensity. Specifically, for the first two weeks' participants complete 2 sets of 8 repetitions for each exercise at 50% of their predicted maximum capacity. For the third and fourth week of training the intensity is increased to 65% with an increase to 3 sets of 8 repetitions.

From the fifth week, the intensity is increased to 75% of the participants predicted maximum capacity. The predicted maximum was a conservatively assumed resistance based on the participant's ability to complete repetitions. At the highest intensity, an accurate resistance was reflected by the participant's capacity to complete eight repetitions before fatigue. This system has been employed safely and effectively in similar populations previously (Henwood et al., 2008; Hewitt et al., 2014). The resistance for each exercise is increased when participants can do 12 repetitions for 3 sets using the correct technique (Henwood et al., 2008).

During the first phase, sessions were delivered in groups of five participants under the supervision of one AEP. As the AEP staff gained more experience in the project and with the delivery, during the subsequent phases, some sessions had increased participant's numbers to accommodate up to eight higher functioning individuals.

Post-PRBT, participants are followed for 24 weeks to assess the residual impact of training on physical, functional and cognitive health. During this period, participants are not restricted in their activities, and are free to become involved in continued gym training or any other exercise or physical activities. However, they are not allowed to continue in the project's gym program, and are not financially supported for alternative exercise programs.

For participants in the EX group, make up sessions are provided within the same week of the missed scheduled session where possible. Participants who discontinue their involvement in the EX group are promptly followed up by telephone and asked about the reasons for dropping out. Participants needed to attend > 50% of all sessions to be included in the final analysis as a member of the EX group.

2.1.5 Control

Participants entering the CON group were asked to continue with their usual activities for a 24-week period. Within this time period there was no restriction on receiving allied health services, attending activity groups or any other physical activities they were not presently receiving or involved in at the baseline randomisation. However, participants were asked not to commit to or become involved in any new ongoing (defined as > 1 session per week) activity groups that they were

not referred to by their GP or specialist. Following the completion of the 24-week control phase, all CON participants' direct entry into the PRBT intervention was the same as described above.

To incentivise continued participation among the CON group, individuals were offered monthly education sessions at Burnie Brae. Sessions were open to all CON participants, lasted approximately one hour, including the ~30-minute educational seminar and a light morning tea. Six seminars were delivered on a monthly rolling schedule, and included topics focusing on nutrition, sedentary behaviour, exercise, chronic disease and assistive devices.

2.2 Data collection

For the group randomised directly into the EX group, quantitative data collection occurred at baseline (week 0), post-intervention (week 24) and after the follow-up period (week 48). For those randomised to the CON group, data were collected at baseline (week 0), post-control (week 24), post-intervention (week 48) and after the follow-up period (week 72). All quantitative data collection was performed by experienced AEP using hand held tablets to reduce intra- and inter-tester data handling, with the exception to the Mini Mental State Exam (PAR, Inc., Lutz, FL) and the EQ-5D3L (EuroQol Group, 1990) that due to licencing restriction are collected in paper form. Qualitative data collection occurred after randomisation (EX group, failed to start), during the intervention (EX group, dropped-out) and post-intervention (EX group, completers) through telephone interviews with participants. All telephone interviews were meticulously diarised by an experienced qualitative researcher, relying on previously used techniques for this target population and following a semi-structured script specific to the scenario (Tuckett, 2007; Tuckett, Hodgkinson, Rouillon, Balil-Lozoya, & Parker, 2015; Tuckett & Stewart, 2003). Additionally, focus group interviews for program staff have also be undertaken. All measures collected and their collection protocols have been shown to be safe and reliable for use in the target population.

2.3 Measures

2.3.1 Primary outcome

The primary outcome of this study is the determination of the economic benefit of PRBT through cost-effectiveness, cost-utility and cost-benefit modelling.

- Cost – Effectiveness
    - Modelling will be conducted comparing the effectiveness of PBRT vs usual care to using the primary clinical outcome of change in client summary score on the Short Physical

Performance Battery (SPPB). Specifically the model will identify the incremental cost-effectiveness (ICER) of providing clients with 24 weeks of PBRT compared to a waiting list control group (business as usual). The ICER is calculated as the difference in cost of implementing PBRT compared with business as usual divided by the difference in means of effectiveness between the two conditions. This technique will identify the cost associated with changing a client's score on the SPPB by one point.

- Cost – Utility
    - This modelling will compare the utility change experienced by clients after receiving PRBT compared with the wait list control. The consumer utility will be derived using the EuroQoL EQ-5D-3L and reported in Quality Adjusted Life Years (QALY's).
- Cost – Benefit
    - This model will identify the total benefit to Australia (in Australian dollars) of providing PRBT, including social benefits gleaned from interviews and willingness to pay evaluations, compared with the wait list control. This model will be employed to evaluate the overall benefit or cost of the intervention to Australian society.

Inputs to the model are health care costs/usage (e.g. medical expenditures, pharmaceuticals, emergency department visits) and the costs of program implementation (capital, transport and staffing costs). For the Cost – Effectiveness model, the perspective is the Australian health care system. In other words, the costs considered are extended to those realised by the Australian Health Care system. For the Cost – Utility & Cost – Benefit models, the perspective is wider to encompass the costs borne by Australian society, including the participant themselves, families, non-health services & transfer costs. The time horizon is a period of at least 48 weeks and therefore any discounting after one year will be set at 5% and indexing at the 2016 level. One and two-way sensitivity analysis will be conducted to identify uncertainties in unit costs and quantities. All costs will be measured in Australian dollars.

2.3.2 Secondary outcomes

2.3.2.1 Quantitative data

- Demographics and health status data were collected from participant records using standard methodologies. Height in centimetres and body mass in kilograms were collected using standard methodologies at each of the nominated assessments by an AEP. Health History data were collected by a standardised questionnaire completed before attending the baseline assessment and questioning (sex, marital status, smoking history, level of education, socioeconomic background,

exercise and medical history, including comorbidities and number and type of medications, hospitalisations in the past 12 months, falls in the past six weeks, living, support and care status, and frequency of GP and specialist visit in the past six weeks). These data were then matched against the participant records, held by their aged care provider and consented to by the individual. Where data were missing, the client was questioned directly. Data were collected at baseline with change in falls and health service utilisation reported by the participant through the completion of a daily diary. Diaries are current for 28 days (4 weeks) and collected data on health system utilisation, activity, falls and sleep. Diaries are managed and monitored by the RM, namely the collection, prompting and turnover for those in the exercise phase, and telephoning to prompt and mailing out of new dairies to those not in the exercise phase. For those individuals performing PBRT, diaries were retuned directly, and for those not attending exercise sessions, diaries were returned by postage paid envelope addressed to the project RM.

- Bioelectrical Impedance Analysis (BIA) (Maltron BF-906, Maltron International Ltd, Rayleigh, UK) is used to estimate volume of fat and lean body mass during supine rest. Muscle mass is calculated from a validated BIA equation (Janssen, Heymsfield, Baumgartner, & Ross, 2000). BIA is quick to sample, non-invasive, and is an extensively validated and accurate measure of muscle mass across all age groups (Cruz-Jentoft et al., 2010).
- Hand grip muscle strength is measured using an isometric Jamar dynamometer (Sammons Preston Roylan, Bolingbrook, IL) and has been correlated with lower extremity muscle power, knee extension torque and calf cross-sectional muscle area. Three trials of the dominant hand are conducted, with the best measure kept for analysis (Schaap et al., 2016).
- Isometric leg extension strength is measured during quantitative assessments for all participants and fortnightly during training for individual in the exercise phase. Measurement is by a 0-500-kilogram strain gauge HUR Performance Recorder (HUR Labs Oy, Tampere, FI) that is fitted to the leg extension machine. With the knee locked at 45^0, participant push against the machine with maximum force and data are presented for recording in kilograms. Participants are given two trials and the best result kept for analysis.
- Physical performance is measured by gait speed, and all three objective self-explanatory Short Physical Performance Battery (SPPB) measures collected (Guralnik et al., 1994; Studenski et al., 2011). These are hierarchical tests of standing balance, a timed 4 metre walk and 5-time repeated chair stands. Measures are collected as per the Guralnik et al. (1994) protocol, and can be analysed as independent measures or as a summary score. The SPPB is a known predictor for loss of mobility, hospitalisation, institutionalisation and mortality (Guralnik et al., 1994; Studenski et al., 2011).
- Sarcopenic Status: Diagnosis of sarcopenia requires the presence of both low muscle mass and low muscle function (muscle strength and/or physical performance). In this study, (a) muscle

mass was measured by BIA, (b) muscle strength by hand grip strength, and (c) physical performance by the SPPB 4 metre walk generated gait speed (Cruz-Jentoft et al., 2010; Landi et al., 2012). The established cut-off points to define low muscle mass are ≥2 standard deviations below the norm of a young healthy population (<8.87 kg/m^2 for men and <6.42 kg/m^2 for women), for low muscle strength <30 and <20 kg for men and women, respectively, and low physical performance via a gait speed of <0.8 m/s (Cruz-Jentoft et al., 2010). In addition to the physical assessment of sacropenia, the SARC-F questionaire (Cao et al., 2014) is being completed in the assessment of tool validity in the target population and an Australian context, and the FRAIL scale (Morley, Malmstrom, & Miller, 2012) is being measured to investigate frailty status, and if a relationship between questionaire-generated sarcopenia and fraility exists.

- Mental health: The Mini-Mental State Examination (MMSE) is used to assess level of cognitive impairment or dementia (Folstein, Folstein, & McHugh, 1975), the Geriatric Depression Scale – Short Form (GDS) to evaluate level of depression (Kurlowicz, 1999) and the Geriatric Anxiety Inventory (GIA) to evaluate level of anxiety (Pachana et al., 2007). From the MMSE, participants are classified as having normal cognition (25–30), mild (21–24), moderate (14–20) or severe (<13) cognitive impairment based on their summary score. From the GDS, participants are classified as without depression (normal (0–4)), or having mild depression (5–8), moderate depression (9–11) or severe depression (12–15) based on their summary score. For anxiety, participant scoring ≤ 8 in the GIA have an absence of clinical anxiety, where those scoring ≥9 have a presence of clinical anxiety.
- Nutritional status: The Mini-Nutritional Assessment Instrument® (MNA®) is used to assess nutritional status without the need for blood analyses. The MNA® consists of four main components (anthropometric, and a global, dietary, and subjective assessment), and is internationally recommended as a nutrition assessment tool in nursing care. (Guigoz, 2006; Saka, Kaya, Ozturk, Erten, & Karan, 2010). Participants are described as having a normal nutritional status (12 – 14), at risk of malnutrition (8 - 11) or being malnourished (0 - 7).
- Falls history and fear: Participants falls were self-reported as part of the Health Status Assessment (See *Demographics and health status* above) and diarised (daily diaries) over the course of the project (See *Demographics and health status* above). In addition, the Activity-Specific Balance Confidence questionnaires is used to assess falls self-efficacy in participants as it is valid for total falls risk and can distinguish between fallers and non-fallers (Mak, Pang, & Mok, 2012; Moore et al., 2011). A fall is defined as an event resulting in a person coming to rest unintentionally on the ground or lower level, not as a result of a major intrinsic event (such as a stroke) or an overwhelming hazard (Lamb, Jorstad-Stein, Hauer, & Becker, 2005).
- Sleep: Sleep and sleep quality is collected by self-reported daily dairy (See Demographics and health status above) and are inclusive of nap times (Reid et al., 2013). Achieving between 7 – 9

house sleep in a 24 hour period was considered optimal sleep (Henwood, Tuckett, Bagadi, & Oliffe, 2015).

- Quality of Life: The EuroQoL EQ-5D-3L is used to measure participant health related quality of life (HRQoL) and to calculate Quality Adjusted Life Years (QALY's). This instrument is an extensively validated and accurate measure of health related quality of life which provides a single index value between 1.0 (perfect health) and 0 (death) (Herdman et al., 2011). It consists of two sections: The first section asks participants to select the response that best describes their health state today from 3 possible statements varying in severity within each of five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety depression). This provides for 243 possible health states. The second section asks the participant to rate their perceived health state today on a Visual Analogue Scale where 100 is the best and 0 is the worst possible imagined health state. The utility index value is determined using an algorithm that incorporates scores from each domain response and Utility weights derived from a representative population. Specific utility weights for the EQ-5D are available for Australia (Viney et al., 2011).
- Attendance: Participants exercise session attendance records formed part of the sustainability analysis. In order to access the HUR machines and their suggested exercise prescription, the participants are required to "swipe on" their exercise card prior to use. This data allows quantification of attendance as well as compliance to the exercise prescription. This data is then matched against session data that is recorded by the RM and allows for the reason for not attending and whether the participant was able to make up the missed session during the same week.
- Adverse events: Participants will be requested to make a record of any adverse events that occur during their participation in the project in their daily log book and to notify the RM about these at the earliest convenience. Adverse events will be categorised on the basis of when they occur (during exercise or assessment sessions, including travel to and from the Burnie Brae centres or during incidental activities) as well as their severity, using a five point scale (National Cancer Institute, 2010). The RM or AEP (for adverse events that occur during exercise or assessment sessions) will provide advice to the participant regarding whether they should be referred to a physician or allied health professional. If a participant is absent from one assessment session or two or more consecutively scheduled training and assessment sessions, the RM will also contact them to ensure the absence is not due to any adverse event. During the exercise and assessment sessions, the AEPs will also routinely ask the participants whether they have experienced any adverse events recently.

2.3.2.2 Qualitative data

The aim of the qualitative phase was to examine perceptions about barriers, facilitators and gain a general evaluation of PRBT participation as a care model in the context of its acceptance, feasibility and sustainability:

- Follow-up telephone interviews are conducted with EX group participants (EX group, failed to start), during the intervention (EX group, dropped out) and post-intervention (EX group, completers) consistent with the project focus on intervention/care model acceptance, feasibility and sustainability;
- Furthermore, EX group participants are asked about their falls, sleep and general mental health in the context of the effect of PRBT participation;
- Additionally, focus group interviews involving centre staff (AEPs and bus drivers) will be undertaken to gain an understanding of their perceptions of the program.

Sampling in qualitative research relies on small numbers with the aim of studying in depth and detail (Tuckett, 2004). A sample size of minimum 48 (19.4% of the overall sample) is sought for EX participants so to obtain views from potential participants who failed to start, dropped out or completed the exercise program. Seeking a richness of data about a particular phenomenon, the sample of EX participants is derived purposefully rather than randomly as purposeful sampling tends to be used in qualitative research.

Typically the broad question(s) are guided by:

1. Tell me what attracted you to the program-why did you join?
2. What works or facilitates the good operation of this exercise (PRBT) program from your point-of-view/experience?
3. Tell me what does not work or is a barrier to a good operation of this exercise (PRBT) program from your point-of-view/experience?
4. What would you change?
5. Talk to me about the exercise and your (a) Sleep/sleeping-rest (b) Mental Health/mood and (c) Falls
6. If we had an opportunity to speak to our Federal Minister for Health, what would be your key message to her about your experiences with this program?
7. How useful or not have you found the 'Exit Package'?

Focus group interviews will also be performed with the AEPs who supervise the exercise and testing sessions as well as all the bus drivers who are responsible for transporting the participants to the exercise facility. All AEPs and bus drivers involved in this project will be invited to participate in these focus groups.

2.4 Sample size and feasibility

The sample size was based on a feasibility of delivery capacity calculation. In brief, it was projected a maximum of 300 adults could be recruited to the study and trained safely and effectively, 200 of whom would serve as controls. Capacity for this population was based on the factors: (i) that five older adults with no PBRT experience could be supervised and supported in any one session by two AEP's, (ii) that participants trained twice weekly for 24 weeks at one of two locations, (iii) that the study employed a modified step wedge design where control participants would flow into exercise, (iv) that delivery would occur in four phases with significant clinic delivery crossover, and (v) that individually transporting participants to and from trainings restricted session times to between 8:30 am and 4 pm, with allowances for staff breaks and leaving availability for makeup sessions. As stated previously, 248 participants have entered the study in the 4 recruitment phases.

The feasibility of achieving these numbers was based in that SVHA holds over 70 Commonwealth supported Home Care Packages (HCP), in the Metro-North area (Brisbane River to Moreton Bay South). Of these 45 are HCP level 2 and 25 are HCP level 4 that cater for individuals with more advanced and or pronounced aged care needs that are typically inclusive of nursing and/or allied health professional services. The balance of participants would be recruited from Burnie Brae, who are responsible for almost 8000 Commonwealth Home Support packages (CHSP) in the Brisbane River to Moreton Bay South area. In contrast to the HCP group, individuals with CHSP support are generally higher functioning and have a greater level of physical capacity, but are accessing services for personal care, home assist and/or modification services.

2.5. Data analysis

2.5.1 Statistical analysis

The primary analysis will be of individual participants' data in the EX versus CON group, adjusted for group baseline differences. The analysis will include:

1) Cost-effectiveness, cost-utility and cost-benefit modelling analyses which will include description and comparison of means and variability between PBRT and waiting list controls.
2) Repeated measures on the quantitative outcome measures between groups at the intervention's two time points. A secondary within EX group analysis will explore what if any residual impact of training was present during the follow-up period.
3) An exploratory analysis using regression analysis will look at relationship between key variable in disability and health care utilisation to identify risk factors.

2.5.2 Qualitative Content Analysis (QCA)

The qualitative content analysis (QCA) to be employed combines numerical orientation of quantitative content analysis and the interpretive orientation of grounded theory (Boyde et al., 2009; Morgan, 1993; Tuckett et al., 2009). In brief, the analysis will extend beyond counting words or phrases to identifying patterns in an attempt to understand meanings, consequences and context, and gain new knowledge and insights. In QCA, codes are sorted into categories premised on how different codes are interrelated, with a view to generating these categories into meaningful clusters (themes). An emphasis is placed on 'interpreting the pattern' found in the codes/categories.

3. Discussion

This clinical trial is designed to determine the relative effectiveness and feasibility of a PRBT based intervention in reducing healthcare costs and improving a range of physical and cognitive health markers for older Australians accessing Government supported aged care packages. We feel confident that the research design selected here has a number of distinguishing features that both maximise the potential for this trial to improve usual care practices for this population and ensure all participants the opportunity to experience the benefits of PRBT. First, PRBT is a proven mode of training with benefits for a wide variety of older adults that could substantially reduce the projected personal and healthcare impacts of increasing population disability (Liu & Latham, 2011). Second, this trial seeks to determine whether the reported ability of PRBT to reduce disability in older adults over a short to medium term duration in university or hospital settings can be observed in a real-world setting namely the two Burnie Brae centres. This is a key component of the trial, in that most large-scale studies that have examined the potential for exercise interventions to improve outcomes for older adults have been conducted in universities or hospitals. While exercise trials conducted in universities and hospitals often have high degrees of internal validity, the external validity (generalisability) of the study may not be overly high, with these programs often discontinuing after the trial is completed. The lack of sustainable older adult focused exercise programs is perhaps one reason why so few older adults regularly perform PRBT (Winett, Williams, & Davy, 2009). Therefore, there needs to be a greater focus on promoting sustainable and accessible community-based exercise programs that have been demonstrated to provide significant physical and psychosocial benefits to their older clients (Henwood, Wooding, & de Souza, 2013; Keogh, Rice, Taylor, & Kilding, 2014). Presently, Burnie Brae offers two self-motivated PRBT exercise clinics for healthy community-dwelling older adults (average age 68.7 years) who regularly train under the guidance of AEPs (> 26 000 sessions per year for over 650 members). If the results of the study are positive, Burnie Brae and other similar aged-friendly community centres will be more likely and better able to integrate PRBT into their usual care practices. Third, the study will use a stepped wedge randomised

controlled trial design. This design was chosen as it is feasible in the real world setting i.e. maximises external validity in the ability to translate these findings into practice while also maintaining a high degree of internal validity. But more importantly, the design is bound in social ethics in that all participants will be provided the opportunity to experience the physical and cognitive benefits of training, a trial outcome often not afforded to the control group in other RCT studies.

We feel this trial is highly significant from a number of perspectives. Recruitment into this study shows a high degree of uptake by eligible individuals and will result in a wide variety of physical and psychosocial benefits to these participants, with many of these benefits expected to be retained to varying extents during the follow-up period (Henwood & Taaffe, 2008). We also believe that such a program will be cost-effective and that it has great potential for altering usual care practices for older adults accessing disability care options throughout the world.

Conflict of Interest

The authors declare that they have no competing interests.

Authors contributions

All authors were involved in the design of the study protocol. The manuscript was prepared by JK and TH with substantial input from the remaining authors. All of the authors reviewed and approved the manuscript prior to submission.

Ethics

Ethics approval was obtained from the University of Queensland Human Research Ethic Committee (Approval number #2015000879) and Gatekeepers approval through the SVHA Human Research Ethic Committee (Approval reference HREC 15/21).

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